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Attorney Docket No. 10233-701.201

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appl. No.	:	10/681,821	Confirmation No.:	6623
Applicant	:	Anant V. HEGDE et al.		
Filing Date	:	October 7, 2003		
Title	:	Vascular Assist Device and Methods		
Group Art Unit	:	3762		
Examiner	:	Joseph A. STOKLOSA		
Docket No.	:	10233-701.201		
Customer No.	:	66854		

APPELLANTS' BRIEF PURSUANT TO 37 C.F.R. § 41.37

MailStop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
Sir:

Appellants submit this brief in accordance with the provisions of 37 C.F.R. § 41.37 in response to the Final Rejection mailed September 5, 2008. Appellants' Notice of Appeal was filed September 23, 2008. This Appeal Brief is therefore timely filed.

The filing fee for this document is being paid via EFS. Please charge any deficit in these fees to Deposit Account No. 50-4050.

I. REAL PARTY IN INTEREST

The real party in interest herein is Pavad Medical, Inc. (Assignee) by virtue of an assignment executed by the inventors (Appellants) to Pavad Medical, Inc. The assignment was recorded by the Assignment Branch of the U.S. Patent and Trademark Office on March 29, 2004 at Reel / Frame 014470 / 0245.

II. RELATED APPEALS AND INTERFERENCES

None.

III. STATUS OF CLAIMS

In the current application under appeal, claims 1-34, 36-39, 122-134 and 136-170 are pending; claims 40-121 and 171-232 are withdrawn from further consideration pursuant to a restriction requirement; and claims 35 and 135 are cancelled.

The rejection of claims 1-34, 36-39, 122-134 and 136-170 is appealed herein.

IV. STATUS OF AMENDMENTS

Appellants have submitted no amendments after the final rejection. All amendments prior to the close of prosecution on the merits have been entered.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Independent claim 1 recites a device having a compliant first layer configured to engage internal vasculature and fabricated with a material having a minimum of 500% elongation and a second layer coupled to the first layer. The second layer has a stiffness greater than the stiffness of the first layer. The first and second layers define a cavity therebetween having a volume, wherein the first layer is configured to be deformed in response to a change in the volume of the cavity. The second layer includes a first end and a second end, the first end and the second end being configured to be removably coupled such that the device is reconfigurable between an uninstalled configuration in which the first and second ends are separate and an installed

configuration in which the first and second ends are coupled. This device is described in at least paragraphs [0055], [0062], [0066]-[0076], [0110]-[0123] and Figures 2-4, 7 and 20-30 of the application as filed.

Independent claim 122 recites a system having a pump, a cuff and a conduit. The pump includes a controller configured to receive a signal associated with the cardiac cycle of the heart. The cuff includes a compliant first layer configured to engage internal vasculature and fabricated with a material having a minimum of 500% elongation. The cuff also includes a second layer having a stiffness greater than a stiffness of the first layer and having an opening formed therein. The compliant first layer and the second layer are coupled to form a cavity bounded by the first layer and the second layer. The cavity is in communication with the opening in the second layer. The second layer also includes a first end and a second end configured to be removably coupled such that the cuff is reconfigurable between an installed configuration in which the first and second ends are separate and an installed configuration in which the first and second ends are coupled. The conduit is coupled between the opening and the pump and is configured to convey a fluid between the pump and the cavity, thereby causing deformation of the first layer by expanding and contracting the cavity. This system is described in at least paragraphs [0055]-[0062], [0066]-[0076], [0110]-[0123] and Figures 2-4, 7 and 20-30 of the application as filed.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Appellants respectfully request the Board of Patent Appeals and Interferences to review the following grounds of rejection on appeal:

1. Whether claims 1-3, 9, 12, 14-17, 19, 20, 26, 27, 31, 36-39, 122, 136-139, 143 and 147-158 are anticipated by Easterbrook et al. US 6,238,334 ("Easterbrook") under 35 U.S.C. § 102(b) or, alternatively, are obvious in view of Easterbrook under 35 U.S.C. § 103(a).

2. Whether claims 4, 7, 8, 10, 11, 13, 18, 28-30, 32-34, 140-142, 144-146, 159, 160, 169 and 170 are patentable in view of Easterbrook under 35 U.S.C. § 103(a).

3. Whether claims 5 and 6 are patentable over Easterbrook in view of Walsh et al. US 6,902,522 ("Walsh") under 35 U.S.C. § 103(a).

4. Whether claims 21-25, 128, 129 and 161-164 are patentable over Easterbrook in view of Franchi US 6,030,335 ("Franchi") under 35 U.S.C. § 103(a).

5. Whether claims 123-127 and 130-134 are patentable over Easterbrook in view of Freed US 5,169,379 ("Freed") under 35 U.S.C. § 103(a).

6. Whether claims 165-168 are patentable over Easterbrook in view of Okuzumi US 6,587,734 ("Okuzumi") under 35 U.S.C. § 103(a).

VII. ARGUMENTS

Appellants respectfully submit that claims 1-34, 36-39, 122-134 and 136-170 are in proper form and are patentable over the prior art of record.

Legal discussion

The Examiner bears the initial burden of establishing a *prima facie* case of nonpatentability under §§ 102 and 103. *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). With respect to rejections under § 102, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP 2131. When a reference is silent about an asserted inherent characteristic, it must be clear that the missing descriptive matter is necessarily present in the method described in the reference and that it would be so recognized by persons of ordinary skill. *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991). "Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981) (quoting *Hansgirg v. Kemmer*, 102 F.2d 212, 214, 40 USPQ 665, 667 (CCPA 1939)).

A *prima facie* case of obviousness requires a determination of (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; and (3) the level of ordinary skill in the pertinent art. *KSR International v. Teleflex*, Inc. 550 U.S. 398, 127. S.Ct. 1727, 167 L.Ed. 705, 710, 82 USPQ2d 1385 (2007), *quoting Graham v. John Deere Co. of Kansas City,* 383 U.S. 1, 17-18 (1966). The obviousness or nonobviousness of the subject matter is determined against this background. *Id.*

To find an invention obvious, the prior art, common knowledge, or the nature of the problem, viewed through the eyes of an ordinary artisan, must have suggested all the elements of the claimed invention. *Dystar Textilfarben GMBH & Co v. C.H. Patrick Co.*, 464 F.3d 1356, 1361 (Fed. Cir. 2006). Likewise, when the prior art teaches away from a combination of elements and features, discovery of a successful means of combining them is more likely to be nonobvious. *KSR,* 167 L.Ed. at 1740. "Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *Id.* at 1741, *quoting In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006).

Rejection of claims 1-3, 9, 12, 14-17, 19, 20, 26, 27, 31, 36-39, 122, 136-139, 143 and 147-158 over Easterbrook under § 102(b) and § 103(a)

The Examiner rejected claims 1-3, 9, 12, 14-17, 19, 20, 26, 27, 31, 36-39, 122, 136-139, 143 and 147-158 under § 102(b) as anticipated by or, in the alternative, under § 103(a) as obvious over Easterbrook. (Final Office Action, ¶¶ 4-20). This rejection is improper and should be overturned for at least the reasons set forth below.

Claim 1

Easterbrook describes a ventricular cuff adapted to be positioned about the heart to assist the mechanical compression of the heart. As shown in Fig. 1, Easterbrook has an outer shell 12 formed from a bendable but non-stretchable material. In one embodiment, the shell has a maximum elongation of 2% of its length, although Easterbrook does point out that a material with a higher percentage elongation may be used. (Easterbrook, Col. 5, lines 39-51). A bladder 14 is formed integrally with the shell and is made from a substantially unyielding and non-stretchable material. (Easterbrook, Col. 6, lines 18-20 and 45-54). The cuff 10 may be wrapped about the heart with the bladder 14 engaging the heart tissue in an uninflated state and fastened into position with fasteners 16. (Easterbrook, Col. 8, lines 2-12). The bladder is inflated and deflated in a pulsatile fashion in synchrony with the heart's systolic and diastolic phases to assist the heart in generating pressure within the ventricles. (Easterbrook, Col. 8, lines 53-57, and Col. 9, lines 9-11).

Easterbrook explicitly distinguishes prior art inflatable ventricular assist devices that use stretchable elastomeric materials. As Easterbrook points out, only a portion of the external fluid pressure applied to prior art elastomeric devices is actually transmitted to the heart; some of the energy from the inflation fluid goes to stretching the elastomeric cup, an action that actually works against the action of the heart. (Easterbrook, Col. 1, line 51 to Col. 2, line 42). Easterbrook specifically chose non-stretchable materials as the material engaging the heart tissue in order to avoid this action. Thus, in the uninflated state, Easterbrook's bladder forms a number of folds which allow the bladder to be displaced radially inwardly when inflated without requiring the bladder to stretch. (Easterbrook, Col. 8, lines 8-12). As fluid pressure increases within the bladder, the bladder unfolds to conform to the exact shape of the heart to apply a uniform pressure to the entire external surface of the ventricles. (Easterbrook, Col. 8, lines 35-43).

The Examiner's anticipation argument for claim 1 fails for at least two reasons. First, claim 1 recites a device having (1) a compliant first layer configured to engage internal vasculature and fabricated with a material having a minimum of 500% elongation, and (2) a second layer coupled to the first layer having a stiffness greater than the stiffness of the first layer. In contrast, Easterbrook's heart-contacting bladder 14 is "substantially unyielding and non-stretchable," and Easterbrook's outer shell has a maximum elongation of 2% or more, thereby making Easterbrook's second layer less stiff than the first layer. (Easterbrook, Col. 5, lines 39-51 and Col. 6, lines 18-20 and 45-54). In the Final Office Action, the Examiner ignored the explicit teaching of Easterbrook and stated that he considers Easterbrook's material to have "properties consistent with 500% elongation." (Final Office Action, ¶ 5). The Examiner offered no support within Easterbrook or elsewhere for this assertion, however. In fact, the Examiner's contention about Easterbrook's material directly contradicts Easterbrook's disclosure of a tissue-engaging layer that is unyielding and non-stretchable.

Second, claim 1 also recites a cavity defined by the first and second layers, wherein the first layer is configured to be deformed in response to a change in the volume of the cavity. Easterbrook, on the other hand, specifically teaches away from deformation of the tissue-engaging layer. The Examiner never addressed this limitation of claim 1, thereby failing to state a *prima facie* case of anticipation of claim 1 by Easterbrook. Because Easterbrook fails to

disclose at least these two explicit limitations of claim 1, Easterbrook cannot anticipate claim 1. Claim 1, and claims 2, 3, 9, 12, 14-17, 19, 20, 26, 27, 31 and 36-39 depending from it, are patentable over Easterbrook under § 102(b).

In his alternative rejection of claim 1 under § 103(a), the Examiner argued that it would have been obvious to provide a material for the first layer with a minimum 500% elongation "to provide the predictable results of increasing compliance of the bladder to the heart and distributing more evenly a pressure across the heart." (Final Office Action, ¶ 6). The Examiner also asserted that (1) this limitation is no more than the discovery of an optimum or workable range of a condition generally disclosed in the prior art; (2) the selection of a material with these properties was mere design choice; and (3) discovery of the value of this material property involves only routine skill in the art. (Final Office Action, ¶ 6). In addition to being a classic example of the use of hindsight by reading the teachings of Appellants' invention into the prior art, the Examiner's arguments directly contradict the explicit teaching of Easterbrook that unstretchable material better distributes forces across the heart. (See Easterbrook, Col. 8, lines 35-43). By failing to articulate a rational basis for reading the limitations of claim 1 into Easterbrook in direct contravention of Easterbrook's explicit disclosure, the Examiner has not meet his burden of stating a *prima facie* basis for the obviousness of claim 1. Claim 1, and claims 2, 3, 9, 12, 14-17, 19, 20, 26, 27, 31 and 36-39 depending from it, are patentable over Easterbrook under § 103(a).

Claim 122

Like claim 1, claim 122 recites a cuff having a compliant first layer configured to engage internal vasculature and fabricated with a material having a minimum of 500% elongation. The cuff also includes a second layer having a stiffness greater than a stiffness of the first layer and having an opening formed therein. As discussed above, Easterbrook's heart-engaging bladder 14 is "substantially unyielding and non-stretchable," and Easterbrook's outer shell has a maximum elongation of 2% or more, thereby making Easterbrook's second layer less stiff than the first layer. (Easterbrook, Col. 5, lines 39-51 and Col. 6, lines 18-20 and 45-54). Easterbrook fails to disclose these explicit limitations of claim 122 and therefore cannot anticipate claim 122.

Claim 122 also recites deformation of the first layer by expanding and contracting the cavity defined by the first and second layer. Easterbrook, on the other hand, specifically teaches away from deformation of the tissue-engaging layer. The Examiner never addressed any of these limitations of claim 122 and therefore failed to state a *prima facie* case of anticipation. Because Easterbrook fails to disclose at least these explicit limitations of claim 122, Easterbrook cannot anticipate claim 122. Claim 122, and claims 136-139, 143 and 147-158 depending from it, are patentable over Easterbrook under § 102(b).

The Examiner also never specifically addressed the obviousness of claim 122 in view of Easterbrook and has therefore not met his burden of establishing a *prima facie* case of obviousness. In fact, Easterbrook teaches away from the subject matter of claim 122, and any attempt to read the limitations of claim122 into Easterbrook would amount to hindsight. Claim 122, and claims 136-139, 143 and 147-158 depending from it, are patentable over Easterbrook under § 103(a).

Rejection of claims 4, 7, 8, 10, 11, 13, 18, 28-30, 32-34, 140-142, 144-146, 159, 160, 169 and 170 over Easterbrook under § 103(a)

The Examiner rejected claims 4, 7, 8, 10, 11, 13, 18, 28-30, 32-34, 140-142, 144-146, 159, 160, 169 and 170 as being obvious in view of Easterbrook. (Final Office Action, ¶¶ 22-30). This rejection is improper and should be overturned for at least the reasons set forth below.

Claims 4, 7, 8, 10, 11, 13, 18 and 28-30

Claims 4, 7, 8, 10, 11, 13, 18 and 28-30 depend from claim 1 and are patentable over Easterbrook under § 103(a) for at least the reasons stated above with respect to claim 1.

In addition, the Final Office Action is unclear about the basis of the rejection of claim 13. Claim 13 depends from claims 1 and 3 and recites materials for the first and second layer as being one of silicone, neoprene and copolymers comprising styrene and butadiene. While the Examiner has rejected claim 13 as being unpatentable over Easterbrook alone under § 103(a), in his remarks regarding claim 13 the Examiner stated that Easterbrook does not disclose any of these materials and that it would have been obvious to modify Easterbrook as taught by Franchi to use such materials. (Final Office Action, ¶ 24). Appellants respectfully request the Examiner to clarify the basis of the rejection of claim 13.

Claims 32-34

Claim 32 depends from claims 1, 26 and 28 and is patentable over Easterbrook under § 103(a) for at least the reasons stated above with respect to claim 1. In addition, claim 32 recites tab widths and tab spacings selected such that when a tab on a first end of the second layer is coupled to a tab on a second end of the second layer, the device encircles a portion of the blood vessel and a side branch coupled to the blood vessel with restricting blood flow into or from the side branch. The Examiner's discussion of the basis of his obviousness rejection of claim 32 never specifically addresses the subject matter of claim 32. (Final Office Action, ¶ 27). The Examiner has therefore failed to state a *prima facie* basis for the obviousness of claim 32.

In fact, Easterbrook neither discloses nor suggests the structure positively recited by claim 32. Easterbrook's device is designed to attach directly to the heart, not to a blood vessel having a side branch. Easterbrook therefore addresses neither the need for accommodating a vessel side branch nor the solution of providing attachment tabs with appropriate widths and spacing. Claim 32, and claims 33 and 34 depending from it, are patentable over Easterbrook under § 103(a) for this reason as well.

Claims 140-142, 159, 160, 169 and 170

Claims 140-142, 159, 160, 169 and 170 depend from claim 122 and are therefore patentable over Easterbrook under § 103(a) for at least the reasons stated above with respect to claim 122.

Claims 144-146

Claim 144 depends from claims 122, 138 and 140 and is patentable over Easterbrook under § 103(a) for at least the reasons stated above with respect to claim 122. In addition, as in claim 32, claim 144 recites tab widths and tab spacings selected such that when a tab on a first end of the second layer is coupled to a tab on a second end of the second layer, the device encircles a portion of the blood vessel and a side branch coupled to the blood vessel with restricting blood flow into or from the side branch. The Examiner's discussion of the basis of his obviousness rejection of claim 144 never specifically addresses the subject matter of claim 144. (Final Office Action, ¶ 27). The Examiner has therefore failed to state a *prima facie* basis for the obviousness of claim 144.

In fact, Easterbrook neither discloses nor suggests the structure positively recited by claim 144. Easterbrook's device is designed to attach directly to the heart, not to a blood vessel having a side branch. Easterbrook therefore addresses neither the need for accommodating a vessel side branch nor the solution of providing attachment tabs with appropriate widths and spacing. Claim 144, and claims 145 and 146 depending from it, are patentable over Easterbrook under § 103(a) for this reason as well.

Rejection of claims 5 and 6 over Easterbrook in view of Walsh

The Examiner rejected claims 5 and 6 under 35 U.S.C. § 103(a) as being unpatentable over Easterbrook in view of Walsh. (Final Office Action, ¶¶ 31-32). Claim 5 depends from claim 1, and claim 6 depends from claim 5.

Walsh describes a jacket conforming to the exterior of a heart to constrain expansion of the heart. Walsh discloses nothing, however, to overcome Easterbrook's deficiencies with respect to the subject matter of claim 1. Specifically, Walsh fails to disclose or suggest a device having a compliant first layer configured to engage internal vasculature and fabricated with a material having a minimum of 500% elongation and a second layer coupled to the first layer having a stiffness greater than the stiffness of the first layer. Walsh also fails to disclose or suggest a device with a cavity defined by such first and second layers, wherein the first layer is configured to be deformed in response to a change in the volume of the cavity. For at least these reasons, claims 5 and 6 are patentable over the combination of Easterbrook and Walsh under § 103(a).

Rejection of claims 21-25, 128, 129 and 161-164 over Easterbrook and Franchi

The Examiner rejected claims 21-25, 128, 129 and 161-164 under 35 U.S.C. § 103(a) as being unpatentable over Easterbrook in view of Franchi. (Final Office Action, ¶¶ 33-36). This rejection is improper and should be overturned for at least the reasons set forth below.

Claims 21-25

Claims 21-25 depend from claims 1, 17 and 19. Franchi describes an implantable heart-assist pump 10 inserted inside the aorta 16. (See Franchi, Fig. 1). Franchi's device has a flexible membrane 18 defining a space 20 into and out of which hydraulic fluid may be injected by a variable pressure source 28 to decrease and increase the volume 22 available to blood flowing

through the device. (Franchi, Col. 3, lines 28-59). As a material for membrane 18, Franchi suggests the use of an elastomer such as silicone or polyurethane. (Franchi, Col. 4, lines 19-20). While Franchi acknowledges that polyurethane elastomers may have elongations of 100%-150%, Franchi specifically states that "it is important to keep the maximum localized elongation to which the material is subjected down to a value that is much smaller, for example deformation that does not exceed 15% at any point of the membrane." (Franchi, Col. 4, lines 28-36).

As discussed above, claim 1 recites a device having a compliant first layer configured to engage internal vasculature and fabricated with a material having a minimum of 500% elongation and a second layer coupled to the first layer having a stiffness greater than the stiffness of the first layer. Franchi explicitly teaches away from this limitation and therefore does not overcome Easterbrook's deficiencies discussed above with respect to the subject matter of claim 1. For at least this reason, claims 21-25 are patentable over Easterbrook and Franchi under § 103(a).

Claim 128

Claim 128 depends from claim 122. Claim 122 recites a cuff having a compliant first layer configured to engage internal vasculature and fabricated with a material having a minimum of 500% elongation. The cuff also includes a second layer having a stiffness greater than a stiffness of the first layer and having an opening formed therein. As discussed above with respect to claims 21-25, Franchi explicitly teaches away from this limitation and therefore does not overcome Easterbrook's deficiencies discussed above with respect to the subject matter of claim 122. For at least this reason, claim 128 is patentable over Easterbrook and Franchi under § 103(a).

Claim 129

Claim 129 depends from claim 122 and is therefore patentable over Easterbrook and Franchi under § 103(a) for the reasons discussed above with respect to claim 128. In addition, claim 129 recites a pump, cuff and conduit that are implantable within a human body, with the pump having a controller configured to receive a signal associated with the cardiac cycle of the heart, as recited in parent claim 122. The Examiner argues that Franchi teaches the use of an implantable pump, but never indicates where in Franchi he finds that disclosure. (Final Office

Action, ¶ 35). In fact, however, Franchi never says whether the variable pressure source 28 and control electronics are implanted or external. (See Franchi, Col. 3, lines 47-59). The Examiner has therefore failed to establish a *prima facie* basis for the obviousness of claim 129 for this reason as well. Claim 129 is patentable over Easterbrook and Franchi under § 103(a).

Claims 161-164

Claims 161-164 depend from claim 122 and are therefore patentable over Easterbrook and Franchi under § 103(a) for the reasons stated above with respect to claim 128. In addition, claim 161 recites a fluid volume compensator as part of the claimed system. The Examiner contends that Franchi discloses a fluid volume compensator (Final Office Action, ¶ 36), but the portion of Franchi's disclosure cited by the Examiner does not support that contention. The only volumes described in Franchi Cols. 3 and 4 are the closed intermediate space 20 and blood flow volume 22 within the cylinder of Franchi's aortic device. In fact, Franchi fails to disclose or suggest this claimed feature. Claims 161-164 are therefore patentable over Easterbrook and Franchi under § 103(a) for this reason as well.

Rejection of claims 123-127 and 130-134 over Easterbrook in view of Freed

The Examiner rejected claims 123-127 and 130-134 under 35 U.S.C. § 103(a) as being unpatentable over Easterbrook in view of Freed. (Final Office Action, ¶¶ 37-38). Claims 123-127 and 130 depend from claim 122, claims 131 and 133 depend from claim 130, claim 132 depends from claim 131 and claim 134 depends from claim 133.

Freed describes a ventricular assist system using a pumping bladder 12 disposed within the patient's aorta 14. (Freed, Col. 6, lines 30-33 and Fig. 1). A bedside console inflates and deflates the bladder. (Freed, Col. 6, line 30, to Col. 8, line 22 and Figs. 1-2). Freed discloses nothing, however, to overcome Easterbrook's deficiencies with respect to the subject matter of claim 122. Specifically, Freed fails to disclose or suggest a device with a cuff having a compliant first layer configured to engage internal vasculature and fabricated with a material having a minimum of 500% elongation. Freed also lacks a cuff with a second layer having a stiffness greater than a stiffness of the first layer and having an opening formed therein. For at least these reasons, claims 123-127 and 130-134 are patentable over the combination of Easterbrook and Freed under § 103(a).

Rejection of claims 165-168 over Easterbrook in view of Okuzumi

The Examiner rejected claims 165-168 under 35 U.S.C. § 103(a) over Easterbrook in view of Okuzumi. (Final Office Action, ¶¶ 39-40). Claims 165-168 depend from claim 122.

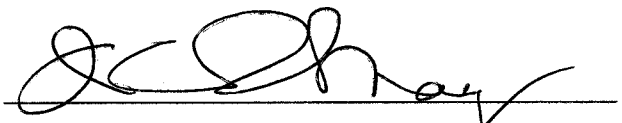
Okuzumi describes an implantable heart sack. Okuzumi discloses nothing to overcome Easterbrook's deficiencies with respect to the subject matter of claim 122. Specifically, Okuzumi fails to disclose or suggest a device with a cuff having a compliant first layer configured to engage internal vasculature and fabricated with a material having a minimum of 500% elongation. Okuzumi also lacks a cuff with a second layer having a stiffness greater than a stiffness of the first layer and having an opening formed therein. For at least these reasons, claims 165-168 are patentable over the combination of Easterbrook and Okuzumi under § 103(a).

CONCLUSION

For the reasons stated above, claims 1-34, 36-39, 122-134 and 136-170 are patentable over the prior art of record, and the rejections of those claims under 35 U.S.C. §§ 102 and 103 are improper and should be withdrawn. Appellants respectfully ask the Board to overturn the Examiner's rejection with instructions to allow the claims.

Respectfully submitted,

Date: November 17, 2008

By: 

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VIII. CLAIMS APPENDIX

1. **(Previously amended)** A device, comprising:

a compliant first layer configured to engage internal vasculature and fabricated with a material having a minimum of 500% elongation;

a second layer coupled to the first layer, the second layer having a stiffness greater than a stiffness of the first layer; and

the first layer and the second layer defining a cavity therebetween, the cavity having a volume wherein the first layer is configured to be deformed in response to a change in the volume of the cavity, wherein the second layer includes a first end and a second end, said first end and said second end configured to be removably coupled such that the device is reconfigurable between an uninstalled configuration in which the first and second ends are separate and an installed configuration in which the first and second ends are coupled.

2. **(Original)** The device of claim 1 wherein the first layer is selectively radially deformed in response to a change in the volume of the cavity.

3. **(Previously amended)** The device of claim 1, wherein the material of the first layer is a first material and the second layer is fabricated with a second material.

4. **(Original)** The device of claim 3, wherein the first material is a first silicone elastomer and the second material is a second silicone elastomer.

5. **(Original)** The device according to claim 1 wherein a portion of the device is coated with a tissue growth inducing polymeric material.

6. **(Original)** The device according to claim 5 wherein the tissue growth inducing material is one of poly-L-lysine and poly-D-lysine.

7. **(Original)** The device of claim 4, wherein the first silicone elastomer is a 5-50 A silicone elastomer having a minimum of 500% elongation.

8. **(Original)** The device of claim 4, wherein the second silicone elastomer is a 65-95 A silicone elastomer having less than a 400% elongation.

9. **(Original)** The device of claim 1 wherein the second layer further comprises a reinforcement element coupled to the second layer such that the reinforcement element is configured to maintain the length and width of the second layer.

10. **(Previously amended)** The device of claim 4, wherein the first material is an elastomer that has hardness of 5-50 shore A.

11. **(Original)** The device of claim 4, wherein the second material is an elastomer that has hardness of 65-95 shore A and having a maximum elongation of 400%.

12. **(Original)** The device of claim 9, wherein the reinforcement element is fabricated from at least one of polyester, nylon, para-aramid fiber, stainless steel, platinum, superelastic nitinol and alloys of nickel and titanium.

13. **(Original)** The device of claim 3, wherein the first and second material are one of silicone, neoprene and copolymers comprising styrene and butadiene.

14. **(Original)** The device of claim 1, wherein the first layer is coupled to the second layer about a perimeter of the first layer.

15. **(Original)** The device of claim 1, wherein the first layer is coupled to the second layer about a portion of the perimeter of the second layer.

16. **(Original)** The device of claim 14, wherein a perimeter of the second layer extends beyond the perimeter of the first layer.

17. **(Original)** The device of claim 1, the second layer further comprising a length and a width, the first layer further comprising a length and a width, wherein the length of the first layer is less than the length of the second layer.

18. **(Original)** The device of claim 17, wherein the width of the first layer is less than the width of the second layer.

19. **(Original)** The device of claim 17 wherein the length of the second layer is sufficient for the second layer to completely encircle a portion of a blood vessel.

20. **(Previously amended)** The device of claim 19 having a second layer further comprising a first end and a second end wherein when the second layer is configured to completely encircle a portion of a blood vessel, the first end and the second end of the second layer overlap.

21. **(Original)** The device of claim 19 wherein the portion of the blood vessel comprises the ascending aorta.

22. **(Original)** The device of claim 19 wherein the portion of the blood vessel comprises the descending aorta.

23. **(Original)** The device of claim 19 wherein the portion of the blood vessel comprises a set of intercostal arteries or a set of intercostal veins.

24. **(Original)** The device of claim 19, wherein the portion of the blood vessel comprises the superior vena cava.

25. **(Original)** The device of claim 19, wherein the portion of the blood vessel comprises the inferior vena cava.

26. **(Original)** The device of claim 1 wherein the second layer further comprising a first end and a second end, wherein each of the first end and the second end have at least two tabs, each of the tabs in the at least two tabs has a width wherein the sum of the widths of all the tabs in the at least two tabs on the first end is less than the width of the device.

27. **(Original)** The device of claim 26, wherein the at least two tabs on the first and second ends are configured to be removably coupled such that the device is reconfigurable between a first configuration in which the at least two tabs on the first and second ends are separate and a second configuration in which the at least two tabs on the first and second ends are coupled.

28. **(Original)** The device of claim 26 wherein a tab spacing profile is provided between adjacent tabs in the at least two tabs, the tab spacing profile having a width wherein the sum of the tab spacing profile widths and the widths of all of the tabs in the at least two tabs equals the width of the device.

29. **(Original)** The device of claim 28 wherein the tab spacing profile between each of the tabs in the at least two tabs is the same.

30. **(Original)** The device of claim 28 having at least two different tab spacing profiles.

31. **(Original)** The device of claim 26 wherein when the device is disposed about a blood vessel in a body at least one of the two or more tabs of the first end is coupled to at least one of the two or more tabs on the second end.

32. **(Original)** The device of claim 28, wherein the tab widths and tab spacing profiles are selected such that when the at least one tab on the first end is coupled to at least one tab on the second end the device encircles a portion of a blood vessel and a side branch coupled to the blood vessel without restricting blood flow into or from the side branch.

33. **(Original)** The device of claim 32, wherein the portion of a blood vessel and a side branch comprises the descending aorta and at least one set of intercostal arteries.

34. **(Original)** The device of claim 32, wherein the portion of a blood vessel and a side branch comprises the inferior vena cava and at least one set of intercostal veins.

35. **(Canceled)**

36. **(Original)** The device of claim 1 wherein the perimeter of the first layer perimeter defines a first shape and the perimeter of the second layer defines a second shape.

37. **(Original)** The device of claim 36 wherein the first shape is similar to the second shape.

38. **(Original)** The device of claim 36 wherein the second shape is rectangular and first shape is a different shape than the second shape.

39. **(Original)** The device of claim 1 further comprising an expandable bladder having a volume and disposed within the cavity and configured such that the first layer is deformed in response to a change in volume of the bladder.

40. **(Withdrawn)** A device, comprising:

an expandable layer configured to engage internal vasculature;

a cover layer coupled to the expandable layer and having a length and a width, the expandable layer and the cover layer defining a cavity therebetween, the cavity having a volume, the cover layer defining an opening in fluid communication with the cavity; and

a reinforcement element coupled to the cover layer and configured to maintain the length and width of the cover layer, wherein, the expandable layer is configured to be selectively deformed in response to a change in the volume of the cavity.

41. **(Withdrawn)** The device of claim 40, wherein selectively deformed is a deformation that is radially selective.

42. **(Withdrawn)** The device of claim 40, selectively deformed is a deformation that is longitudinally selective.

43. **(Withdrawn)** The device of claim 40, wherein the first layer is fabricated with a first material having a first stiffness and the second layer is fabricated with a second material having a second stiffness.

44. **(Withdrawn)** The device of claim 43 wherein the second stiffness is greater than the first stiffness.

45. **(Withdrawn)** The device of claim 44, wherein the first material is a first silicone elastomer and the second material is a second silicone elastomer.

46. **(Withdrawn)** The device of claim 45, wherein the first silicone elastomer is a 5-50 A silicone elastomer having a minimum of 500% elongation.

47. **(Withdrawn)** The device of claim 45, wherein the second silicone elastomer is a 65-95 A silicone elastomer having less than a 400% elongation.

48. **(Withdrawn)** The device of claim 40, wherein the reinforcement element is at least one of polyester, nylon, para-aramid fiber, stainless steel, platinum, superelastic nitinol and alloys of nickel and titanium.

49. **(Withdrawn)** The device of claim 45, wherein the first material is an elastomer that has hardness of 5-50 shore A and having a minimum elongation of 500%.

50. **(Withdrawn)** The device of claim 45, wherein the second material is an elastomer that has hardness of 65-95 shore A and having a maximum elongation of 400%.

51. **(Withdrawn)** The device of claim 43, wherein the first material and second material are one of silicone, neoprene and copolymers comprising styrene and butadiene.

52. **(Withdrawn)** The device of claim 40, wherein the device is reconfigurable between a first, substantially planar configuration and a second, substantially tubular configuration.

53. **(Withdrawn)** The device of claim 52, further comprising a connection member joining a first portion of the cover layer to a second portion of the cover layer when the device is in the second configuration.

54. **(Withdrawn)** The device of claim 40, wherein the cover layer includes a first end and a second end, said first end and said second end configured to be removably coupled such that the device is reconfigurable between a first configuration in which the first and second ends are separate and a second configuration in which the first and second ends are coupled.

55. **(Withdrawn)** The device of claim 54 wherein when the first end and the second end are coupled the first end and the second end are in an overlapping configuration that encircles a portion of a blood vessel.

56. **(Withdrawn)** The device of claim 55 wherein the portion of the blood vessel comprises the ascending aorta.

57. **(Withdrawn)** The device of claim 55 wherein the portion of the blood vessel comprises the descending aorta.

58. **(Withdrawn)** The device of claim 55 wherein the portion of the blood vessel comprises a set of intercostal arteries or a set of intercostal veins.

59. **(Withdrawn)** The device of claim 55, wherein the portion of the blood vessel comprises the superior vena cava.

60. **(Withdrawn)** The device of claim 55, wherein the portion of the blood vessel comprises the inferior vena cava.

61. **(Withdrawn)** The device of claim 40 wherein the cover layer further comprises a first end and a second end, wherein each of the first end and the second end have at least two tabs, each of the tabs in the at least two tabs has a width wherein the sum of the widths of all the tabs in the at least two tabs on the first end is less than the width of the device.

62. **(Withdrawn)** The device of claim 61, wherein the at least two tabs on the first and second ends are configured to be removably coupled such that the device is reconfigurable between a first configuration in which the at least two tabs on the first and second ends are separate and a second configuration in which the at least two tabs on the first and second ends are coupled.

63. **(Withdrawn)** The device of claim 61 wherein a tab spacing profile is provided between adjacent tabs in the at least two tabs, the tab spacing profile having a width wherein the sum of the tab spacing profile widths and the widths of all of the tabs in the at least two tabs equals the width of the device.

64. **(Withdrawn)** The device of claim 63 wherein the tab spacing profile between each of the tabs in the at least two tabs is the same.

65. **(Withdrawn)** The device of claim 63 having at least two different tab spacing profiles.

66. **(Withdrawn)** The device of claim 61 wherein when the device is disposed about a blood vessel in a body at least one of the two or more tabs of the first end is coupled to at least one of the two or more tabs on the second end.

67. **(Withdrawn)** The device of claim 63, wherein the tab widths and tab spacing profiles are selected such that when the at least one tab on the first end is coupled to at least one tab on the second end the device encircles a portion of a blood vessel and a side branch coupled to the blood vessel without restricting blood flow into or from the side branch.

68. **(Withdrawn)** The device of claim 67, wherein the portion of a blood vessel and a side branch comprises the descending aorta and at least one set of intercostal arteries.

69. **(Withdrawn)** The device of claim 67, wherein the portion of a blood vessel and a side branch comprises the inferior vena cava and at least one set of intercostal veins.

70. **(Withdrawn)** The device of claim 54, wherein the first end and the second end include cooperating portions of a mating fastener.

71. **(Withdrawn)** The device of claim 54, wherein the first end and the second end are configured to be sewn together.

72. **(Withdrawn)** The device of claim 70, wherein the mating fasteners are magnets.

73. **(Withdrawn)** The device of claim 70, wherein at least one of the mating fasteners is magnetic.

74. **(Withdrawn)** The device of claim 70, wherein a one the mating fasteners is a magnet and the other mating fastener is formed from a magnetically attractive material.

75. **(Withdrawn)** The device of claim 70, wherein the mating fasteners are opposite sides of a buckle.

76. **(Withdrawn)** The device of claim 70, wherein the mating fasteners are a screw and a screw-receiving opening.

77. **(Withdrawn)** The device of claim 70 wherein the mating fasteners are a hook and a loop.

78. **(Withdrawn)** The device of claim 70 wherein the mating fasteners comprise a plurality of hooks and a plurality of loops.

79. **(Withdrawn)** The device of claim 70 wherein the mating fasteners include a locking ring and a mating element.

80. **(Withdrawn)** The device of claim 70 wherein the mating fasteners include a positive-locks.

81. **(Withdrawn)** The device of claim 40, further comprising:
a conduit coupled to the second layer in communication with the opening, the conduit configured to be coupled to a pump.

82. **(Withdrawn)** The device of claim 81 wherein one of a fluid is configured to be selectively communicated in synchronization with the cardiac cycle to the cavity via a conduit in communication with the opening in the cover layer.

83. **(Withdrawn)** A vascular assist device configured to be coupled to at least a portion of a blood vessel, the device comprising:

a vascular engaging layer;

an expandable layer,

a cover layer; and

the device having an uninstalled configuration and an installed configuration; wherein,

the vascular engaging layer is disposed between the outer wall of the blood vessel and the expanding layer,

the cover layer and the expanding layer are coupled so as to form a cavity therebetween, the cavity being bounded by the expanding layer and the cover layer;

the cover layer having an opening formed therein, the opening being in communication with the cavity and the cavity being configured to selectively receive a fluid via the opening whereby the fluid causes the volume of the cavity to change wherein the change in cavity volume causes the expanding layer to deform more than the cover layer to accommodate the change in cavity volume.

84. **(Withdrawn)** A vascular assist device according to claim 83 wherein the vascular engaging layer is sufficiently long to encircle a portion of the blood vessel.

85. **(Withdrawn)** A vascular assist device according to claim 83 wherein the expandable layer is sufficiently long to at least partially encircle a portion of the blood vessel.

86. **(Withdrawn)** A vascular assist device according to claim 83 wherein the vascular engaging layer is coupled to the expandable layer.

87. **(Withdrawn)** The device of claim 83, wherein the vascular engaging layer is fabricated with a first material, the expanding layer is fabricated with second material and the cover layer is fabricated with a third material different from the first and second material.

88. **(Withdrawn)** The device of claim 83, wherein the vascular engaging layer is a vascular graft.

89. **(Withdrawn)** The device of claim 88, wherein the vascular graft is made from a polymer selected from the group consisting of: polyester, nylon, polytetrafluoroethylene and polyvinylidene fluoride.

90. **(Withdrawn)** The device of claim 83, wherein the second material is a first silicone elastomer and the third material is a second silicone elastomer.

91. **(Withdrawn)** The device of claim 83, wherein the cover layer further comprises a reinforcement element selected from the group consisting of: polyester, nylon, para-aramid fiber, stainless steel, platinum, superelastic nitinol and alloys of nickel and titanium.

92. **(Withdrawn)** The device of claim 83 wherein the expanding layer and the cover layer are fabricated from a material selected from the group consisting of: silicone, neoprene, copolymers comprising styrene and copolymers comprising butadiene.

93. **(Withdrawn)** The device of claim 83, wherein the perimeter of the expanding layer is coupled to the cover layer.

94. **(Withdrawn)** The device of claim 93, wherein the perimeter of the expanding layer aligns with a portion of the perimeter of the cover layer.

95. **(Withdrawn)** The device of claim 83, wherein the device is repeatably configurable between the uninstalled configuration and the installed configuration.

96. **(Withdrawn)** The device of claim 95 wherein the cover layer further comprises at least one pair of cooperative fastening elements.

97. **(Withdrawn)** The device of claim 96 wherein when the device is in the uninstalled configuration the at least one pair of cooperative fastening elements are uncoupled.

98. **(Withdrawn)** The device of claim 96 wherein when the device is in the installed configuration the at least one pair of cooperative fastening elements are coupled.

99. **(Withdrawn)** The device of claim 96 wherein one of the fastening elements in the at least one pair of cooperative fastening elements comprises a plurality of fastening positions such that the size of the device in the installed configuration may be adjusted by changing to which of said plurality of fastening positions the other fastening element is coupled.

100. **(Withdrawn)** The device of claim 83 wherein the cover layer includes a first end and a second end, said first end and said second end configured to be removeably coupled such that the device is reconfigurable between an uninstalled configuration in which the first and second ends are separate and an installed configuration in which the first and second ends are coupled.

101. **(Withdrawn)** The device of claim 83 wherein the device is maintained in an installed configuration about a portion of a blood vessel by suturing a first portion of the vascular engaging layer to a second portion of the vascular engaging layer.

102. **(Withdrawn)** The device according to claim 83 wherein a portion of the device is coated with a tissue growth inducing polymeric material.

103. **(Withdrawn)** The device according to claim 102 wherein the tissue growth inducing polymeric material is one of poly-L-lysine and poly-D-lysine.

104. **(Withdrawn)** A vascular assist device configured to be coupled to at least a portion of a blood vessel, the device comprising:

a vascular engaging layer having a first stiffness;

a cover layer having a second stiffness that is greater than the first stiffness and being coupled to the vascular engaging layer such that a portion of the cover layer extends past at least a portion of the perimeter of the vascular engaging layer; the cover layer and the vascular engaging layer forming a cavity therebetween, the cover layer having an opening formed therein

in communication with the cavity, the cavity being configured to selectively receive a fluid via the opening; and

the device having an uninstalled configuration and an installed configuration.

105. **(Withdrawn)** A vascular assist device according to claim 104 wherein the vascular engaging layer is sufficiently long to at least partially encircle a portion of the aorta.

106. **(Withdrawn)** A vascular assist device according to claim 104 wherein the vascular engaging layer is sufficiently long to at least partially encircle a portion of the vena cava.

107. **(Withdrawn)** The device of claim 104, wherein the vascular engaging layer is fabricated with a first material and the cover layer is fabricated with a second material different from the first material.

108. **(Withdrawn)** The device of claim 107, wherein the first material is a first silicone elastomer and the second material is a second silicone elastomer.

109. **(Withdrawn)** The device of claim 104, wherein the cover layer further comprises a reinforcement element selected from the group consisting of: polyester, nylon, para-aramid fiber, stainless steel, platinum, superelastic nitinol and alloys of nickel and titanium.

110. **(Withdrawn)** The device of claim 107, wherein the first and second material are one of silicone, neoprene, copolymers comprising styrene and copolymers comprising butadiene silicone, neoprene and copolymers comprising styrene and butadiene.

111. **(Withdrawn)** The device of claim 104, wherein the perimeter of the vascular engaging layer is coupled to the cover layer.

112. **(Withdrawn)** The device of claim 111, wherein the perimeter of the vascular engaging layer aligns with a portion of the perimeter of the cover layer.

113. **(Withdrawn)** The device of claim 111, wherein the perimeter of the cover layer extends beyond the perimeter of the vascular layer.

114. **(Withdrawn)** The device of claim 104, wherein the device is repeatably configurable between the uninstalled configuration and the installed configuration.

115. **(Withdrawn)** The device of claim 114 wherein the cover layer further comprises at least one pair of cooperative fastening elements.

116. **(Withdrawn)** The device of claim 115 wherein when the device is in the uninstalled configuration the at least one pair of cooperative fastening elements are uncoupled.

117. **(Withdrawn)** The device of claim 115 wherein when the device is in the installed configuration the at least one pair of cooperative fastening elements are coupled.

118. **(Withdrawn)** The device of claim 115 wherein one of the fastening elements in the at least one pair of cooperative fastening elements comprises a plurality of fastening positions such that the size of the device in the installed configuration may be adjusted by changing to which of said plurality of fastening positions the other fastening element is coupled.

119. **(Withdrawn)** The device of claim 104 wherein the cover layer includes a first end and a second end , said first end and said second end configured to be removeably coupled such that the device is reconfigurable between an uninstalled configuration in which the first and second ends are separate and an installed configuration in which the first and second ends are coupled.

120. **(Withdrawn)** The device according to claim 104 wherein a portion of the device is coated with a tissue growth inducing polymeric material.

121. **(Withdrawn)** The device according to claim 120 wherein the tissue growth inducing polymeric material is one of poly-L-lysine and poly-D-lysine.

122. **(Previously amended)** A system, comprising:

a pump having a controller configured to receive a signal associated with the cardiac cycle of a heart;

a cuff comprising,

a compliant first layer configured to engage internal vasculature and fabricated with a material having a minimum of 500% elongation;

a second layer coupled to the first layer and having a stiffness greater than a stiffness of the first layer and having an opening formed therein;

the compliant first layer and the second layer being coupled to form a cavity bounded by the first layer and the second layer, the cavity being in communication with the opening in the second layer, wherein the second layer includes a first end and a second end, said first end and said second end configured to be removably coupled such that the cuff is reconfigurable between an uninstalled configuration in which the first and second ends are separate and an installed configuration in which the first and second ends are coupled; and

a conduit coupled between the opening and the pump, the conduit configured to convey a fluid between the pump and the cavity thereby causing deformation of the first layer by expanding and contracting the cavity.

123. **(Original)** The system of claim 122 wherein the signal associated with the cardiac cycle is related to systole.

124. **(Original)** The system of claim 122 wherein the signal associated with the cardiac cycle is related to diastole.

125. **(Original)** The system of claim 122 wherein the signal associated with the cardiac cycle is related to a change in aortic pressure.

126. **(Original)** The system of claim 122 wherein the signal associated with the cardiac cycle is related to a change in arterial pressure.

127. **(Original)** The system of claim 122 wherein the signal associated with the cardiac cycle is related to a change in venous pressure.

128. **(Original)** The system of claim 122 wherein the pump is a pulsitile pump.

129. **(Original)** The system of claim 122 wherein the pump, cuff and conduit are implantable within a human body.

130. **(Original)** The system of claim 122 further comprising a sensor configured to generate a signal associated with the cardiac cycle of a heart.

131. **(Original)** The system of claim 130 herein the sensor is a pressure sensor.

132. **(Original)** The system of claim 131 wherein the sensor is part of the cuff.

133. **(Original)** The system of claim 130 wherein the sensor is an electrical sensor.

134. **(Original)** The system of claim 133 wherein the sensor is part of the cuff.

135. **(Canceled)**

136. **(Previously presented)** The system of claim 122 wherein the installed configuration comprises a plurality of coupling positions whereby the size of the cuff may be adjusted by changing into which one of the plurality of coupling positions the first and second ends are coupled.

137. **(Previously amended)** The system of claim 122, wherein the material of the first layer is a first material and the second layer is fabricated with a second material different from the first material.

138. **(Original)** The device of claim 122 wherein the second layer further comprising a first end and a second end, wherein each of the first end and the second end have at least two tabs, each of the tabs in the at least two tabs has a width wherein the sum of the widths of all the tabs in the at least two tabs on the first end is less than the width of the cuff.

139. **(Original)** The device of claim 138, wherein the at least two tabs on the first and second ends are configured to be removably coupled such that the device is reconfigurable between a first configuration in which the at least two tabs on the first and second ends are separate and a second configuration in which the at least two tabs on the first and second ends are coupled.

140. **(Original)** The device of claim 138 wherein a tab spacing profile is provided between adjacent tabs in the at least two tabs, the tab spacing profile having a width wherein the sum of the tab spacing profile widths and the widths of all of the tabs in the at least two tabs equals the width of the device.

141. **(Original)** The device of claim 140 wherein the tab spacing profile between each of the tabs in the at least two tabs is the same.

142. **(Original)** The device of claim 140 having at least two different tab spacing profiles.

143. **(Original)** The device of claim 138 wherein when the device is disposed about a blood vessel in a body at least one of the two or more tabs of the first end is coupled to at least one of the two or more tabs on the second end.

144. **(Original)** The device of claim 140, wherein the tab widths and tab spacing profiles are selected such that when the at least one tab on the first end is coupled to at least one tab on the

second end the device encircles a portion of a blood vessel and a side branch coupled to the blood vessel without restricting blood flow into or from the side branch.

145. **(Original)** The device of claim 144, wherein the portion of a blood vessel and a side branch comprises the descending aorta and at least one set of intercostal arteries.

146. **(Original)** The device of claim 144, wherein the portion of a blood vessel and a side branch comprises the inferior vena cava and at least one set of intercostal veins.

147. **(Original)** The system of claim 122, wherein the conduit further comprises a first end configured to have a single lumen and a second end configured to have a plurality of lumens.

148. **(Original)** The system of claim 147, wherein each lumen has the same diameter.

149. **(Original)** The system of claim 147, wherein at least one lumen has a diameter different from the diameter of another lumen.

150. **(Original)** The system of claim 122, wherein the cavity is coupled to a plurality of conduits.

151. **(Original)** The system of claim 150, wherein one of the plurality of conduits supplies fluid from the pump to the cavity.

152. **(Original)** The system of claim 151, wherein another one of the plurality of conduits returns fluid from the cavity to the pump.

153. **(Original)** The system of claim 122, wherein the conduit has a first diameter adjacent to the opening and a second different diameter at a point distal to the opening.

154. **(Previously amended)** The system of claim 122, wherein the conduit communicates with a plurality of additional conduits wherein at least one of the conduits in the plurality of additional conduits has a diameter that is different from the diameter of at least one other of the plurality of additional conduits.

155. **(Original)** The system of claim 137, wherein the first material is a first silicone elastomer and the second material is a second silicone elastomer.

156. **(Original)** The system of claim 122 wherein the fluid is a liquid is selected from the group consisting of: saline, water, glycols, a combination comprising a glycol and saline and a combination comprising a glycol and water.

157. **(Original)** The system of claim 122 wherein the fluid is a gas that is chemically inert with the first and second layers.

158. **(Original)** The system of claim 157 wherein the fluid is a gas that is one of either carbon dioxide or nitrogen.

159. **(Original)** The system of claim 122 wherein the fluid is a gas having lower density than air.

160. **(Original)** The system of claim 159 wherein the gas is helium.

161. **(Original)** The system of claim 122 further comprising a fluid volume compensator.

162. **(Original)** The system of claim 161 wherein the fluid compensator is disposed in a fluid flow path between the pump and the cavity.

163. **(Original)** The system of claim 161 wherein the fluid compensator is configured to adjust the fluid volume ported into the cavity during activation of the cuff.

164. **(Original)** The system of claim 161 wherein the fluid compensator is configured to allow replenishment of the fluid in the system.

165. **(Original)** The system of claim 122 wherein a surface of one of the cuff, conduit and pump in contact with the fluid are coated with a material to enhance lubricity.

166. **(Original)** The system of claim 122 wherein a surface of one of the cuff, conduit and pump in contact with the fluid is coated with a material to reduce fluid evaporation.

167. **(Original)** The system of claim 122 wherein an interior surface of one of the cuff, conduit and pump is coated with a material to reduce fluid loss.

168. **(Original)** The system of claim 122 wherein a surface of one of the cuff, conduit and pump is coated with a material to reduce fluid loss.

169. **(Previously presented)** The system of claim 122 wherein the conduit further comprises a reinforcement element.

170. **(Original)** The system of claim 169 wherein the reinforcement element is selected from the group consisting of: polyester, nylon, para-aramid fiber, stainless steel, platinum, superelastic nitinol and alloys of nickel and titanium.

171. **(Withdrawn)** A method for augmenting blood flow in a patient body using a cuff formed from a first layer joined to a second layer so that a cavity exists between the layers such that filling the cavity preferentially deforms the first layer, the method comprising:

detecting a first cardiac cycle trigger,

porting a fluid into the cavity so as to elastically deform the first layer thereby compressing a blood vessel in response to the first cardiac cycle trigger; and

porting a fluid out of the cavity in response to a second cardiac cycle trigger.

172. **(Withdrawn)** A method for augmenting blood flow in a body according to claim 171 wherein the first cardiac trigger is related to an ECG of the patient.

173. **(Withdrawn)** A method for augmenting blood flow in a body according to claim 171 wherein the first cardiac trigger is related to the increasing portion of the R-wave.

174. **(Withdrawn)** A method for augmenting blood flow in a body according to claim 173 wherein the first cardiac trigger occurs at 90% of the increasing R-wave amplitude.

175. **(Withdrawn)** A method for augmenting blood flow in a body according to claim 171 wherein the first cardiac trigger is related to the ECG of the patient and selected so that the step of porting a fluid into the cavity so as to elastically deform the first layer coincides with the ventricular systole.

176. **(Withdrawn)** A method for augmenting blood flow in a body according to claim 171 wherein the second cardiac cycle trigger is a predetermined time limit.

177. **(Withdrawn)** A method for augmenting blood flow in a body according to claim 171 wherein the second cardiac cycle trigger is based on the R-R interval.

178. **(Withdrawn)** A method for augmenting blood flow in a body according to claim 171 wherein the second cardiac cycle trigger is related to aortic pressure.

179. **(Withdrawn)** A method for augmenting blood flow in a body according to claim 171 wherein the first and the second cardiac cycle triggers are selected to operate the cuff in copulsation mode.

180. **(Withdrawn)** A method for augmenting blood flow in a body according to claim 171 wherein the cavity inflates during the ventricular systole of the heart.

181. **(Withdrawn)** A method for augmenting blood flow in a body according to claim 171 wherein the first cardiac trigger is related to the Q-T interval.

182. **(Withdrawn)** A method for augmenting blood flow in a body according to claim 171 wherein the first cardiac trigger is related to the decreasing portion of the T-wave.

183. **(Withdrawn)** A method for augmenting blood flow in a body according to claim 182 wherein the first cardiac trigger occurs at the end of the T-wave.

184. **(Withdrawn)** A method for augmenting blood flow in a body according to claim 171 wherein the first cardiac trigger is related to the T-wave and selected so that the step of porting a fluid into the cavity so as to elastically deform the first layer coincides with the ventricular diastole.

185. **(Withdrawn)** A method for augmenting blood flow in a body according to claim 181 wherein the second cardiac cycle trigger is a predetermined time limit.

186. **(Withdrawn)** A method for augmenting blood flow in a body according to claim 181 wherein the second cardiac cycle trigger is based on the R-R interval.

187. **(Withdrawn)** A method for augmenting blood flow in a body according to claim 181 wherein the second cardiac cycle trigger is related to aortic pressure.

188. **(Withdrawn)** A method for augmenting blood flow in a body according to claim 171 wherein the first and the second cardiac cycle triggers are selected to operate the cuff in counterpulsation mode.

189. **(Withdrawn)** A method for augmenting blood flow in a body according to claim 171 wherein the cavity inflates during the ventricular diastole of the heart.

190. **(Withdrawn)** A method for augmenting blood flow in a body using a cuff formed from a first layer joined to a second layer so that a cavity exists between the layers such that filling the cavity preferentially deforms the first layer, the method comprising:

detecting a cardiac cycle trigger;

porting a fluid into the cavity so as to elastically deform the first layer thereby compressing a blood vessel in response to the cardiac cycle trigger; holding the vessel compressed for known duration and

porting a fluid out of the cavity at the end of the duration in order to allow the vessel to relax.

191. **(Withdrawn)** A method for augmenting blood flow in a body according to claim 190 wherein the cardiac trigger is related to the ECG.

192. **(Withdrawn)** A method for augmenting blood flow in a body according to claim 190 wherein the cardiac trigger is related to the increasing portion of the R-wave of the ECG.

193. **(Withdrawn)** A method for augmenting blood flow in a body according to claim 192 in a copulsation manner wherein the first cardiac trigger occurs at 90% of the increasing R-wave amplitude.

194. **(Withdrawn)** A method for augmenting blood flow in a body according to claim 190 in a copulsation manner wherein the cardiac trigger is related to the aortic pressure and selected so that the step of porting a fluid into the cavity so as to elastically deform the first layer coincides with the ventricular systole.

195. **(Withdrawn)** A method for augmenting blood flow in a body according to claim 190 in counterpulsation manner, wherein the cardiac trigger is related to detecting R-wave of the ECG, computing the Q-T interval and triggering the pump to coincide with the end of the T-wave for

porting the fluid into the cavity so as to elastically deform the first layer and compress the blood vessel.

196. **(Withdrawn)** A method for augmenting blood flow in a body according to claim 190 in counterpulsation manner, wherein the cardiac trigger is related to detecting the peak aortic pressure and computing the duration for the aortic valve to close and triggering the pump for porting the fluid into the cavity so as to elastically deform the first layer and compress the blood vessel to coincide with the aortic valve closing.

197. **(Withdrawn)** A method for augmenting blood flow in a vessel of a patient using a cuff having a compliant first layer that at least partially encircles a vessel adjacent the cuff, a second layer coupled to the first layer, the first layer and the second layer defining a cavity therebetween, the method comprising:

changing the pressure of a fluid in the cavity based on a signal associated with the cardiac cycle;

deforming the first layer in response to the changing pressure of the fluid in the cavity; and

deforming the walls of a vessel at least partially encircled by the first layer in response to the deforming of the first layer.

198. **(Withdrawn)** A method for augmenting blood flow in a vessel according to claim 197 wherein the signal associated with the cardiac cycle is related to the ECG of the patient.

199. **(Withdrawn)** A method for augmenting blood flow in a vessel according to claim 197 wherein the signal associated with the cardiac cycle is related to the increasing portion of the R-wave.

200. **(Withdrawn)** A method for augmenting blood flow in a vessel according to claim 197 wherein the signal associated with the cardiac cycle is related to the ECG of the patient and

selected so that the step of deforming the walls of a vessel at least partially encircled by the first layer in response to the deforming of the first layer coincides with the ventricular systole.

201. **(Withdrawn)** A method for augmenting blood flow in a vessel according to claim 197 wherein the signal associated with the cardiac cycle is related to aortic pressure.

202. **(Withdrawn)** A method for augmenting blood flow in a vessel according to claim 197 wherein the changing the pressure of a fluid in the cavity is selected such that the blood flow in the vessel is augmented in a copulsation mode.

203. **(Withdrawn)** A method for augmenting blood flow in a vessel according to claim 197 wherein the changing the pressure of a fluid in the cavity is occurring so that the pressure in the cavity is increasing during the ventricular systole of the heart.

204. **(Withdrawn)** A method for augmenting blood flow in a vessel according to claim 197 wherein the signal associated with the cardiac cycle is related to the Q-T interval.

205. **(Withdrawn)** A method for augmenting blood flow in a vessel according to claim 197 wherein the signal associated with the cardiac cycle is related to the decreasing portion of the T-wave.

206. **(Withdrawn)** A method for augmenting blood flow in a vessel according to claim 197 wherein the signal associated with the cardiac cycle occurs at the end of the T-wave.

207. **(Withdrawn)** A method for augmenting blood flow in a vessel according to claim 197 wherein the signal associated with the cardiac cycle is related to the T-wave and selected so that the step of changing the pressure of a fluid in the cavity coincides with the ventricular diastole.

208. **(Withdrawn)** A method for augmenting blood flow in a vessel according to claim 197 wherein the changing the pressure of a fluid in the cavity is selected such that the blood flow in the vessel is augmented in a counterpulsation mode.

209. **(Withdrawn)** A method for augmenting blood flow in a vessel according to claim 197 wherein the changing the pressure of a fluid in the cavity is occurring so that the pressure in the cavity is increasing during the ventricular diastole of the heart.

210. **(Withdrawn)** A method for augmenting blood flow in a vessel according to claim 197 wherein increasing the pressure in the cavity results in deforming the first layer so as to constrict the vessel.

211. **(Withdrawn)** A system, comprising:

a plurality of cuffs, each of the plurality of cuffs including

a compliant first layer configured to engage internal vasculature;

a second layer coupled to the first layer, the first layer and the second layer defining a cavity therebetween, the second layer defining an opening in communication with the cavity; and a connector configured to couple the plurality of cuffs to one another.

212. **(Withdrawn)** The system of claim 211, wherein the connector is coupled to the second layer of each of the plurality of cuffs.

213. **(Withdrawn)** The system of claim 211, wherein the connector further comprises a conduit coupled between the connector and an opening.

214. **(Withdrawn)** The system of claim 211, wherein at least one of the plurality of cuffs is coupled to the vasculature of a body.

215. **(Withdrawn)** The system of claim 214, wherein at least one of the plurality of cuffs is coupled to an organ in a body.

216. **(Withdrawn)** The system of claim 211 wherein at least one of the plurality of cuffs is configured to engage with at least one set of intercostal arteries.

217. **(Withdrawn)** The system of claim 211 wherein at least one of the plurality of cuffs is configured to engage with at least one set of intercostal veins.

218. **(Withdrawn)** The system of claim 211 wherein at least one of the plurality of cuffs is configured to engage with the ascending aorta.

219. **(Withdrawn)** The system of claim 211 wherein at least one of the plurality of cuffs is configured to engage with the descending aorta.

220. **(Withdrawn)** The system of claim 211, wherein plurality of cuffs are configured to engage with the superior vena cava.

221. **(Withdrawn)** The system of claim 211, wherein plurality of cuffs are configured to engage with the inferior vena cava.

222. **(Withdrawn)** The system of claim 211, wherein each of the plurality of cuffs is repeatably configurable between an uninstalled configuration and an installed configuration.

223. **(Withdrawn)** The system of claim 222 wherein the second layer of each of the plurality of cuffs further comprises at least one pair of cooperative fastening elements.

224. **(Withdrawn)** The system of claim 223 wherein when a cuff is in the uninstalled configuration the at least one pair of cooperative fastening elements are uncoupled.

225. **(Withdrawn)** The system of claim 223 wherein when a cuff is in the installed configuration the at least one pair of cooperative fastening elements are coupled.

226. **(Withdrawn)** The system of claim 223 wherein one of the fastening elements in the at least one pair of cooperative fastening elements comprises a plurality of fastening positions such

that the size of the cuff in the installed configuration may be adjusted by changing to which of said plurality of fastening positions the other fastening element is coupled.

227. **(Withdrawn)** The system of claim 211 wherein the second layer of each of the plurality of cuffs includes a first end and a second end, said first end and said second end configured to be removeably coupled such that the cuff is reconfigurable between an uninstalled configuration in which the first and second ends are separate and an installed configuration in which the first and second ends are coupled.

228. **(Withdrawn)** The system of claim 211 further comprising:
a pump in communication with the connector; and
a controller for providing control signals to the pump in response to triggering signals from a cardiac cycle.

229. **(Withdrawn)** The system of claim 228 configured so that each of the plurality of cuffs is operated sequentially.

230. **(Withdrawn)** The system of claim 228 configured so that each of the plurality of cuffs is operated simultaneously.

231. **(Withdrawn)** The system of claim 228 configured so that each of the plurality of cuffs is operated to augment blood flow in the internal vasculature in a counterpulsation mode.

232. **(Withdrawn)** The system of claim 228 configured so that each of the plurality of cuffs is operated to augment blood flow in the internal vasculature in a copulsation mode.

IX. EVIDENCE APPENDIX

Easterbrook et al. US 6,238,334 cited by the Examiner in an Office Action dated 11/8/2007

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Franchi US 6,030,335 cited by the Examiner in an Office Action dated 5/15/2007

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X. RELATED PROCEEDINGS APPENDIX

None.